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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/125,031 03/10/99 LONGACRE-ANDRE

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HM22/0313
OBLON SPIVAK MCCLELLAND MAIER & NEUSTADT
1755 JEFFERSON DAVIS HIGHWAY
FOURTH FLOOR
ARLINGTON VA 22202

EXAMINER

ART UNIT	PAPER NUMBER
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1641
DATE MAILED:

03/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/125,031

Applicant
LONGACRE-ANDRE et al.

Examiner
James L. Grun, Ph.D.

Group Art Unit
1641



☒ Responsive to communication(s) filed on 03 Aug and 20 Dec 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 46-64 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 46-64 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Center 1600, Group 1640, Art Unit 1641.

The amendments filed 03 August and 20 December 2000 are acknowledged and have been entered. Claims 46-64 are newly added. Claims 1-45 have been cancelled. Claims 46-64 remain in the case. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed. When formal drawings are submitted, the draftsman will perform a review. Direct any inquiries concerning drawing review to the Drawing Review Branch at (703) 305-8404.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention, and failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

The specification is objected to and claims 46-64 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons of record that: the specification does not reasonably provide enablement for every possible polynucleotide or baculovirus construct of the scope as instantly claimed; and, the disclosure is also not enabling for an invention of the scope as instantly claimed wherein those N-terminal MSP-1 sequences critical or essential to the practice of the invention are

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not included in the claims. As set forth, Applicant provides guidance only to the constructs as found in the deposited viruses given CNCM registration numbers I-1659, I-1660, I-1661, I-1662, and I-1663. Absent further description and guidance from Applicant, one would not know what other sequences or vectors were encompassed, and, in particular, one would not know what was encompassed by the vectors as are now recited in claim 55. Again, note that an enabling disclosure for the preparation and use of only a few analogs of a product does not enable all possible analogs where the characteristics of the analogs are unpredictable. As also set forth, the constructs appear to require nucleic acids encoding at least the N-terminal signal sequence of the MSP-1 protein for expression by recombinant baculovirus in Sf9 cells (Longacre et al., Mol. Biochem. Parasitol. 64:191, 1994; see page 201, column 2). Of the MSP-1 sequences as now claimed, only SEQ ID NO: 7 appears to include the relevant sequences. Moreover, the function of no signal sequence other than that of the MSP-1 protein is taught by Applicant in the invention and the ability of another signal sequence to result in appropriate expression of the protein would seem unknown and unpredictable. Thus, one would have no assurance of the ability to make and use constructs which function in the invention in the absence of these required sequences.

Further, claims 52 and 62 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant does not describe a polypeptide having the sequence of SEQ ID NO: 9 as having the relevant signal sequence as is now claimed. Indeed,

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Applicant discloses (see page 16 and Fig. 1D) that the signal sequence has been cut out of SEQ ID NO: 9. It appears that only the sequence of SEQ ID NO: 7 of those sequences now claimed includes the relevant necessary N-terminal sequences. Absent additional written description and guidance from Applicant, one would not be able to practice the invention as instantly claimed.

Applicant's arguments filed 03 August 2000 have been fully considered but they are not deemed to be persuasive. Applicant's assertion that the instant claims are now fully enabled was not found persuasive for the reasons set forth above.

Claims 47, 50, 52, and 55 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons of record in the prior rejection of claim 39 wherein a deposit requirement was made and applicants were deemed not to be in compliance with the Deposit rules. The declaration of Madame Berneman, filed 03 August 2000, is noted and has satisfied many of the deposit requirements. Applicant is reminded, however, that information regarding the deposits, such as the name and address of the depository, in addition to the accession numbers of the deposits and the date(s) of the deposits, **must** be added to the specification by means of filing an amendment as required by 37 CFR §1.809(d).

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Claims 49, 53, and 56-64 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 49 and 59, "said glycosylphosphatidylinositol" lacks antecedent basis. It is suggested that --said glycosylphosphatidylinositol coding sequence-- be substituted therefor.

In claims 53 and 63, "the...Duffy binding protein" and "the...EBA-175 protein" lack antecedent basis.

In claims 56-64, "the...terminal fragment" lacks antecedent basis

Claims 46, 48, 51, 54, 56, 58, 61, and 64 are rejected under 35 U.S.C. § 102(b) as being anticipated by Longacre et al (Mol. Biochem. Parasitol. 64:191, 1994) in light of the instant disclosure, for reasons of record in the prior rejection of the similar subject matter of claims 25-39.

Applicant's arguments filed 03 August 2000 have been fully considered but they are not deemed to be persuasive.

Applicant urges that Longacre et al do not disclose a polynucleotide having a GC content of 40-60% because the sequence has only 33% GC. This is not found persuasive as the argument is drawn to the sequence of the *Plasmodium falciparum* MSP-1 encoding sequence and not to the *Plasmodium vivax* MSP-1 sequence of the reference.

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Claims 46, 48, 51, 54-56, 58, 61, and 64 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the combined teachings of Chappel et al (Mol. Biochem. Parasitol. 60:303, 1993), Miller et al (Mol. Biochem. Parasitol. 59:1, 1993), and Longacre et al (Mol. Biochem. Parasitol. 64:191, 1994), for reasons of record in the prior rejection of the similar subject matter of claims 25-39.

Applicant's arguments filed 03 August 2000 have been fully considered but they are not deemed to be persuasive.

Applicant urges that the declaration of Dr. Longacre-Andre under 37 CFR § 1.132, filed 03 August 2000, provides sufficient evidence of unobvious and unpredictable advantages to overcome the rejection. This is not found persuasive as the showing in the declaration is incommensurate in scope with the invention as claimed in the instantly rejected claims. Polynucleotides encoding the MSP-1 proteins of a variety of plasmodial parasites fall, without modification, into the recited range and to construct vectors for the reasonably expected successful expression of these proteins would have been obvious guided by the teachings of the references. Further, as set forth, one would have expected many polynucleotides of the genus specifically encoding the known sequence of the *P. falciparum* MSP-1 protein to function in such vectors as taught in the references. Moreover, it is not clear that the range of total G+C alone can be used as predictive of expression, as the specific sequence shown to be expressed by Applicant was apparently modified based upon preferred codon usage in Sf9 cells and not merely upon G+C content. Although not sufficient to overcome the invention as broadly claimed, the showing in the

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declaration has, however, been found sufficient to overcome any rejection, under 35 U.S.C. § 103(a) over Chappel et al, Miller et al, and Longacre et al, of the specific *P. falciparum* polynucleotides as instantly claimed. One would have had no guidance to select the sequence species as instantly claimed from the genus of encoding sequences and would not have expected the increased expression of the protein encoded thereby in Sf9 cells as shown in the declaration.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A SHORTENED STATUTORY PERIOD FOR REPLY TO THIS FINAL ACTION IS SET TO EXPIRE **THREE MONTHS** FROM THE MAILING DATE OF THIS ACTION. IN THE EVENT A FIRST REPLY IS FILED WITHIN **TWO MONTHS** OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE **THREE-MONTH** SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR REPLY EXPIRE LATER THAN **SIX MONTHS** FROM THE MAILING DATE OF THIS FINAL ACTION.

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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to James L. Grun, Ph.D., whose telephone number is (703) 308-3980. The Examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Long Le, SPE, can be contacted at (703) 305-3399. The fax phone numbers for official communications to Group 1640 are (703) 305-3014 or (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



James L. Grun, Ph.D.
March 7, 2001



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641